

Project 2970- Proposed

Department of Health

12VAC5-410 Regulations for the Licensure of Hospitals in Virginia (amending 12VAC5-410-10 and 12VAC5-410-60).

12VAC5-412. Regulations for Licensure of Abortion Facilities (adding 12VAC5-412-10 through 12VAC5-412-370).

Part I

Definitions and General Information and Procedures

Article 1

Definitions

12VAC5-410-10. Definitions.

As used in this chapter, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

"Board" means the State Board of Health.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Commissioner" means the State Health Commissioner.

"Consultant" means one who provides services or advice upon request.

"Department" means an organized section of the hospital.

"Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.

"Facilities" means building(s), equipment, and supplies necessary for implementation of services by personnel.

"Full-time" means a 37-1/2 to 40 hour work week.

"General hospital" means institutions as defined by § 32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

"Home health care department/service/program" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12VAC5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Medical" means pertaining to or dealing with the healing art and the science of medicine.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing home" means an institution or any identifiable component of any institution as defined by § 32.1-123 of the Code of Virginia with permanent facilities that include inpatient beds and whose primary function is the provision, on a continuing basis, of nursing and health related services for the treatment of patients who may require various types of long term care, such as skilled care and intermediate care.

"Nursing services" means patient care services pertaining to the curative, palliative, restorative, or preventive aspects of nursing that are prepared or supervised by a registered nurse.

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Organized" means administratively and functionally structured.

"Organized medical staff" means a formal organization of physicians and dentists with the delegated responsibility and authority to maintain proper standards of medical care and to plan for continued betterment of that care.

"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. ~~Outpatient abortion clinics are deemed a category of outpatient hospitals.~~

"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns or controls the physical facilities and/or manages or operates a hospital.

"Rural hospital" means any general hospital in a county classified by the federal Office of Management and Budget (OMB) as rural, any hospital designated as a critical access hospital, any general hospital that is eligible to receive funds under the federal Small Rural Hospital Improvement Grant Program, or any general hospital that notifies the commissioner of its desire to retain its rural status when that hospital is in a county reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

"Service" means a functional division of the hospital. Also used to indicate the delivery of care.

"Special hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g., tuberculosis, orthopedic, pediatric, maternity).

"Special care unit" means an appropriately equipped area of the hospital where there is a concentration of physicians, nurses, and others who have special skills and experience to provide optimal medical care for patients assigned to the unit.

"Staff privileges" means authority to render medical care in the granting institution within well-defined limits, based on the individual's professional license and the individual's experience, competence, ability and judgment.

"Unit" means a functional division or facility of the hospital.

12VAC5-410-60. Separate license.

A. A separate license shall be required by hospitals maintained on separate premises even though they are operated under the same management. Separate license is not required for separate buildings on the same grounds or within the same complex of buildings.

B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, and outpatient surgery, outpatient abortions, surgery).

CHAPTER 412 REGULATIONS FOR LICENSURE OF ABORTION FACILITIES

Part I Definitions and Requirements for Licensure

12VAC5-412-10. Definitions.

The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:

"Abortion" means the use of an instrument, medicine, drug, or other substance or device with the intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than a live birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this definition.

"Abortion facility" means a facility in which five or more first trimester abortions per month are performed.

"Administrator" means the person appointed by the governing body as having responsibility for the overall management of the abortion facility. Job titles may include director, executive director, office manager, or business manager.

"Commissioner" means the State Health Commissioner.

"Department" means the Virginia Department of Health.

"First trimester" means the first twelve weeks from conception based on an appropriate clinical estimate by a licensed physician.

"Informed written consent" means the knowing and voluntary written consent to an abortion by a pregnant woman of any age in accordance with Virginia Code § 18.2-76.

"Licensee" means the person, partnership, corporation, association, organization, or professional entity who owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.

"Minor" means a patient under the age of 18.

"Patient" means any person seeking or obtaining services at an abortion facility.

"Physician" means a person licensed to practice medicine in Virginia.

"Spontaneous miscarriage" means the expulsion or extraction of a product of human conception resulting in other than a live birth and which is not an abortion.

"Trimester" means a 12-week period of pregnancy.

12VAC5-412-20. General.

A license to establish or operate an abortion facility shall be issued only when the abortion facility is in compliance with all applicable federal, state and local statutes and regulations, the provisions of this chapter, and when the application fee has been received by the department.

No person or entity shall establish, conduct, maintain, or operate in this state, any abortion facility without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.

12VAC5-412-30. Classification.

Abortion facilities shall be classified as a category of hospital.

12VAC5-412-40. Separate license.

An abortion facility operating at more than one location shall be required to obtain separate licenses for each location in which abortion services are provided.

Abortion facilities which have separate organized sections, units or buildings to provide services of a classification covered by provisions of other state statutes or regulations shall be required to have any additional applicable license required for that type or classification of service.

Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of these regulations.

12VAC5-412-50. Request for issuance.

A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to the Department's Office of Licensure and Certification (OLC).

B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days.

C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.

D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee is submitted.

E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC.

F. A license shall not be assigned or transferred. A new application for licensure shall be made at least 30 days in advance of a change of ownership or location.

12VAC5-412-60. License expiration and renewal.

A. Licenses shall expire at midnight April 30th following the date of issue, and shall be renewable annually, upon filing of a renewal application and payment of the appropriate nonrefundable renewal application fee. Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter.

B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.

C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal.

D. Any license issued before April 30, 2012 shall not expire until April 30, 2013. No additional fee will be required for the period from May 1, 2012 until April 30, 2013.

12VAC5-412-70. Return and/or Reissuance of License.

A. It is the responsibility of the facility's governing body to maintain a current and accurate license at all times.

B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.
6. Change of operator.

Notices shall be sent to the attention of the director of the OLC.

C.. The license issued by the commissioner shall be returned to the OLC when any of the changes listed in subsection B of this section occur. In addition, if the abortion facility is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within 5 calendar days of the abortion facility closing. The abortion facility's patients and the OLC shall be notified where all patient records will be located.

D. The OLC shall determine if any changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the facility during the process of evaluating a change.

E. The facility will be notified in writing by the OLC whether a license can be re-issued or a new application is needed.

12VAC5-412-80. Allowable variances.

A. The commissioner may authorize a temporary variance only to a specific regulation of this Chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular regulation or requirements contained in a particular regulation of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current regulation constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the requirements that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.

B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well being of patients.

C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.

D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation to which the temporary variance was granted shall be resumed.

12VAC5-412-90. Right of entry.

Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any such employee shall properly identify himself or herself as an inspector designated by OLC; the abortion facility may verify the identity of the inspector prior to his or her admission. Such entries and inspections shall be made with the permission of the owner or person in charge, unless an inspection warrant is obtained after denial of entry from an appropriate circuit court. If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate revocation or suspension of the license. If the entity is unlicensed, the owner or person in charge shall be subject to penalties and other actions pursuant to §32.1-27 of the Code of Virginia.

12VAC5-412-100. On-site inspection.

A. An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than biennially. If the department finds, after inspection, non-compliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-110.

B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction or supervision. If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the abortion facility before removal.

C. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records, is not available on the premises, such person or the designated alternate, shall be available on the premises within 1 hour of the surveyor's arrival. A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within 2 hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-27 and denial, suspension or revocation of the facility's license in accordance with 12VAC5-412-130.

12VAC5-412-110. Plan of correction.

A. Upon receipt of a written licensing report, each abortion facility shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.

B. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan of correction as determined by the OLC. The plan of correction shall contain for each violation cited:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
2. The expected correction date, not to exceed 30 working days from the exit date of the survey;
3. A description of the measures implemented to prevent a recurrence of the violation; and
4. The signature of the person responsible for the validity of the report.

C. The administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with Virginia Code § 32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.

D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-412-120. OLC complaint investigations.

A. The OLC shall investigate any complaints regarding alleged violations of this chapter and applicable law. When the investigation is complete the abortion facility and the complainant, if known, will be notified of the findings of the investigation.

B. As required by the OLC, the administrator shall submit a plan of correction for any deficiencies found during a complaint investigation in accordance with 12 VAC 5- 412- 110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-412-130. Violation of this chapter or applicable law; Denial, revocation or suspension of license.

A. When the department determines that an abortion facility is (i) in violation of any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility. in accordance with § 32.1-135 of the Code of Virginia.

B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provisions of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.

C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license.

D. The abortion facility has the right to contest the denial, revocation or suspension of a license in accordance with the provisions of the Administrative Process Act (Virginia Code § 2.2-4000 et seq.).

Part II
Organization and Management

12VAC5-412-140. Management and administration

A. The abortion facility shall comply with:

1. This chapter (12VAC5 412);
2. Other applicable federal, state or local laws and regulations; and
3. The abortion facility's policies and procedures.

B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.

C. The abortion facility shall permit OLC inspectors to conduct inspections to:

1. Verify application information;
2. Determine compliance with this chapter and applicable law;
3. Review necessary records and documents; and
4. Investigate complaints.

D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.
6. Change of operator.

Notices shall be sent to the attention of the director of the OLC.

E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.

12VAC5-412-150. Governing body.

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the abortion facility.

B. There shall be disclosure of abortion facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.

C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.

D. The governing body shall have a formal organizational plan with written bylaws. These shall clearly set forth organization, duties and responsibilities, accountability, and relationships of professional staff and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.

E. The bylaws shall include at a minimum the following:

1. A statement of purpose;
2. Description of the functions and duties of the governing body, or other legal authority;
3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;
4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and
5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.

12VAC5-412-160. Policies and procedures.

A. Each abortion facility shall develop, implement and maintain documented policies and procedures, which shall be readily available on the premises, and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but shall not be limited to the following topics:

1. Personnel;
2. Types of elective services performed in the abortion facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining informed written consent of the patient pursuant to §18.2-76 prior to the initiation of any procedures;
6. When to use sonography to assess patient risk;
7. Infection prevention;
8. Quality and risk management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state, and local laws;
12. Abortion facility security;
13. Disaster preparedness;
14. Patient rights;
15. Functional safety and abortion facility maintenance; and
16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.

B. These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request.

12VAC5-412-170. Administrator.

A. The governing body shall select an administrator who shall be responsible for the managerial, operational, financial and reporting components of the abortion facility, including but not limited to:

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;

2. Employing qualified personnel and ensuring appropriate personnel orientation, training education and evaluation;

3. Ensuring the accuracy of public information materials and activities;

4. Ensuring an effective budgeting and accounting system is implemented; and

5. Maintaining compliance with applicable laws and regulations and implementing corrective action.

B. Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing.

C. A qualified individual shall be appointed in writing to act in the absence of the administrator.

12VAC5-412-180. Personnel.

A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.

B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable.

C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

D. The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

E. Job Descriptions.

1. Written job descriptions that adequately describe the duties of every position shall be maintained.

2. Each job description shall include position title, authority, specific responsibilities and minimum qualifications.

3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.

F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.

G. Personnel policies and procedures shall include, but not be limited to:

1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;

2. Process for verifying current professional licensing or certification and training of employees or independent contractors;

3. Process for annually evaluating employee performance and competency;

4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and

5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.

12VAC5-412-190. Clinical staff.

A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and non-physician health care practitioners shall be clearly defined.

B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience.

C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility.

D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.

12VAC5-412-200. Patients' rights.

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

B. The abortion facility shall establish and maintain complaint handling procedures which specify the:

1. System for logging receipt, investigation and resolution of complaints; and
2. Format of the written record of the findings of each complaint investigated.

C. The abortion facility shall designate staff responsible for complaint resolution, including:

1. Complaint intake, including acknowledgment of complaints;
2. Investigation of the complaint;
3. Review of the investigation findings and resolution for the complaint; and
4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.

D. Any patient seeking an abortion shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service.

E. The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:

1. Abortion facility contact person; and
2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.

F. The abortion facility shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained for no less than three years.

Part III

Quality Management and Infection Prevention

12VAC5-412-210. Quality management.

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment

and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:

1. A physician;
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff.

In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.

D. Measures shall be implemented to resolve problems or concerns that have been identified.

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

12VAC5-412-220. Infection prevention.

A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.
2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.
3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

B. Written infection prevention policies and procedures shall include, but not be limited to:

1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility;
2. Training of all personnel in proper infection prevention techniques;
3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;
4. Use of standard precautions;

5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration;
6. Use of personal protective equipment;
7. Use of safe injection practices;
8. Plans for annual retraining of all personnel in infection prevention methods;
9. Procedures for monitoring staff adherence to recommended infection prevention practices; and
10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

C. Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.

D. The abortion facility shall have an employee health program that includes:

1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood borne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;
5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

E. The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities:

1. A procedure for surveillance, documentation and tracking of reported infections; and

2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.

Part IV
Patient Care Management

12VAC5-412-230. Patient services; patient counseling.

A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician.

B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to §16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

C. A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant to the provisions of §18.2-76 of the Code of Virginia.

D. When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.

E. The abortion facility shall offer each patient seeking an abortion, in a language or manner they understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.

F. There shall be an organized discharge planning process that includes an evaluation of the patient's capacity for self-care and discharge instructions for patients to include instructions to call or return if signs of infection develop.

12VAC5-412-240. Medical testing and laboratory services.

A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to §18.2-76, shall be completed for each patient.

1. Use of any additional medical testing shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.

2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.

4. A written report of each laboratory test and examination shall be a part of the patient's record.

B. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).

1. Facilities for collecting specimens shall be available on site.

2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.

3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.

C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.

D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9 VAC20-120).

12VAC5-412-250. Anesthesia service.

A. The anesthesia service shall comply with the Office-Based Anesthesia provisions of the Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).

B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.

C. When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration.

D. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 B:

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;
5. Continuous electrocardiograph;
6. Devices for measuring blood pressure, heart rate and respiratory rate;
7. Defibrillator; and
8. Accepted method of identifying and preventing the interchangeability of gases.

E. Elective general anesthesia shall not be used.

F. If deep sedation, or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until the patient meets the discharge criteria.

G. In addition to the requirements of subsection D of this section, an abortion facility administering, deep sedation or a major conductive block, or administering general anesthesia in an emergent situation shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 C:

1. Drugs to treat malignant hyperthermia, when triggering agents are used;
2. Peripheral nerve stimulator, if a muscle relaxant is used; and
3. If using an anesthesia machine, the following shall be included:
 - a. End-tidal carbon dioxide monitor (capnograph);
 - b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;
 - c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
 - d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;
 - e. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;
 - f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered;
 - g. Alarm systems for high (disconnect), low (subatmospheric) and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and

h. A gas evacuation system.

H. The abortion facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria.

12VAC5-412-260. Administration, storage and dispensing of drugs.

A. Controlled substances, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).

B. Drugs, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed or administered by a physician.

C. Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.

D. The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.).

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Drug Control Act of the Code of Virginia.

12VAC5-412-270. Equipment and supplies.

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:

1. A bed or recliner suitable for recovery;
2. Oxygen with flow meters and masks or equivalent;
3. Mechanical suction;
4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways;
5. Emergency medications, intravenous fluids, and related supplies and equipment;
6. Sterile suturing equipment and supplies;
7. Adjustable examination light;
8. Containers for soiled linen and waste materials with covers; and
9. Refrigerator.

12VAC5-412-280. Emergency equipment and supplies.

An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support. Drugs shall include, at a minimum, those to treat the following conditions:

1. Cardiopulmonary arrest;
2. Seizure;
3. Respiratory distress;
4. Allergic reaction;
5. Narcotic toxicity;
6. Hypovolemic shock; and
7. Vasovagal shock.

12VAC5-412-290. Emergency services.

A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for resuscitation and control of hemorrhage and other complications.

B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support.

C. A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.

Part V

Support Services

Health Information Records And Reports

12VAC5-412-300. Health Information records.

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
 - a. Physician orders;
 - b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
 - c. Anesthesia record;
 - d. Operative record;
 - e. Surgical medication and medical treatments;
 - f. Recovery room notes;
 - g. Physician and nurses' progress notes;
 - h. Condition at time of discharge;
 - i. Patient instructions, preoperative and postoperative; and
 - j. Names of referral physicians or agencies; and
6. Any other information required by law to be maintained in the health information record.

12VAC5-412-310. Records storage.

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

12VAC5-412-320. Required Reporting.

A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120).

B. The abortion facility shall report the following events to OLC:

1. Any patient, staff or visitor death.
2. Any serious injury to a patient.
3. Medication errors that necessitate a clinical intervention other than monitoring;
4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and
5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 U.S.C. §301 et seq. - PL 101-629).

C. Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the:

1. Abortion facility name;
2. Type and circumstance of the event being reported;
3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies.

E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC except as required or permitted by law.

F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.

Part VI
Functional Safety and Maintenance

12VAC5-412-330. Abortion Facility Security and Safety.

The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to:

1. Abortion facility security;
2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and
3. Provisions for disseminating safety-related information to employees and users of the abortion facility.

12VAC5-412-340. Disaster preparedness.

A. Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

B. An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

12VAC5-412-350. Maintenance.

A. The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

12VAC5-412-360. Fire-fighting equipment and systems.

A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.

B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.

C. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).

Part VII

Design and Construction

12VAC5-412-370. Local and state codes and standards.

Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001.

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.

In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.

All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation.

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings.